

REMARKS

Reconsideration and withdrawal of the requirement for restriction and election of species are respectfully requested in view of the remarks herewith. As this paper is submitted within the one-month term for reply set by the December 4, 2001 Office Action, no fee is believed to be owed. In the event, however, a fee is due, the Assistant Commissioner is authorized to charge such fee, or credit any overpayment, to Deposit Account 50-0320.

The December 5, 2001 Office Action required an election under 35 U.S.C. § 121 from:

- Group I** Claims 1-14, 20 and 21-25 drawn to a vector comprising a LMW PEI and a DNA, and methods of making the vector, and use of the vector, classified in class 435, subclass 320.1, and class 514, subclass 44;
- Group II** Claims 27-31, drawn to the use of pharmaceutical compositions comprising a LMW PEI and a DNA, and an *in vivo* gene therapy method comprising the step of administering to any subject a vector comprising a LMW PEI and a DNA, classified in class 514, subclass 44;
- Group III** Claims 26 and 33, drawn to an *ex vivo* gene therapy method comprising the step of administering to any subject genetically modified cells expressing a DNA which is transfected by a vector comprising a LMW PEI and the DNA, classified in class 435, subclass 325, and class 424, subclass 93.21; and
- Group IV** Claims 15-19 and 32, drawn to a process for preparing a LMW PEI, pharmaceutical compositions comprising the LMW PEI, classified in class 424, subclass 486.

In response to the restriction requirement, Applicants provisionally elect **Group I**, claims 1-14, 20 and 21-25 drawn to a vector comprising a LMW PEI and a DNA, and methods of making the vector, and use of the vector, classified in class 435, subclass 320.1, and class 514, subclass 44, for further prosecution in this application.

This election is made *with traverse* and is made without prejudice to Applicants' right to file divisional applications directed to the non-elected subject matter. It is respectfully requested that the restriction requirement be favorably reconsidered and withdrawn.

The Office Action further requires a "three-tiered" election of species (if Applicants elect the claims of Group I) as follows:

Species Election I:

- (a) the vector of claim 1, which is a viral nucleic construct; and
- (b) the vector of claim 1, which is a non viral construct;

Species Election II:

- (a) an effector gene selected from the group consisting of the coding sequence of a pharmacological active compound or its prodrug form,
- (b) an effector gene encoding an enzyme, and
- (c) the coding sequence of a fusion protein comprising an enzyme fused to a cell-specific ligand; and

Species Election III:

- (a) the vector of claim 1, wherein the ratio by weight of LMW PEI to nucleic acid is 3: 1 or more; and
- (b) the vector of claim 1, wherein the ratio by weight of LMW PEI to nucleic acid is 8:1 or more.

In response to this three-tiered species election requirement, Applicants provisionally elect the following species for further searching in this application:

- I (b) the vector of claim 1 which is a non viral construct;
- II (b) the vector of claim 8, wherein at least one effector gene encodes an enzyme; and
- III (a) the vector of claim 1, wherein the ratio by weight of LMW PEI to nucleic acids is 3:1 or more.

Claims 1-14, 20 and 21-25 are readable upon the elected species.

The requirement for this three-tiered election of species is also respectfully traversed since the species are each related to one another and directed to the same inventive concept which may be searched simultaneously. It is Applicants' understanding that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species

which are written in dependent form or otherwise include all of the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141.

Applicants respectfully urge that the Restriction Requirement does not establish that searching all the inventions would constitute an undue burden to the Patent Office. Moreover, Applicants urge that the Restriction Requirement is contrary to public policy. Accordingly, Applicants submit that the Restriction Requirement is improper and should be withdrawn or at least modified.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

Applicants urge that the Restriction Requirement does not meet the second of these criteria as the search for all of the groups overlaps. One of the reasons for this is that Group I shares the same classification as Groups II and III. Further, Group IV is directed to a process for preparing the LMW PEI recited in Group I. Thus, reconsideration and modification the Restriction Requirement are warranted.

The present claims represent a web of knowledge and continuity of effort that merit examination in a single application. It is respectfully urged, therefore, that restricting the claims in the manner suggested in the Restriction Requirement constitutes an undue burden to Applicants as well as to the public. The cost of prosecuting and maintaining so many patents is unreasonable in view of the fact that the three groups are so closely related. Further, the public is inconvenienced as they will not know whether or not Applicants will file a divisional application

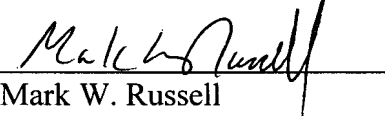
to the remaining subject matter. Thus, the public will not know if they can practice the remaining invention without infringing future patent applications.

Accordingly, in view of the foregoing, reconsideration and withdrawal of the restriction and election of species requirements are requested, and an early action on the merits is earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By:



Mark W. Russell

Reg. No. 37,514

Samuel H. Megerditchian

Reg. No. 45,678

(212) 588-0800